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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,352	03/21/2001	Luis Lopez-Molina	2312-109	3472

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/813,352

Applicant(s)

LOPEZ-MOLINA ET AL.

Examin r

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed April 19, 2004 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 17, 2004 has been entered.

Claims 1-24 and 30-37 are cancelled.

Claims 25-27 are currently amended.

Claims 39-44 are newly added.

Claims 25-29 and 38-44 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 28-29 and 39-42 recites the limitation "in comparison to an untransformed plant" in line 2. There is insufficient antecedent basis for this

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limitation in the claims, since the claims from which they depend (claims 25-27) are not directed to transformed plants.

Claims 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 43-44 recites the limitation "The seed, seedling or plant of claim 37" in line 1. There is insufficient antecedent basis for this limitation in the claims, since claim 37 has been cancelled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-29 and 38-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a seed, seedling or plant comprising a polynucleotide which comprises a promoter operatively linked to a nucleic acid sequence encoding abscisic acid insensitive 5 (ABI5).

Claims 25-29 and 38-42, as written, do not sufficiently distinguish over seeds, seedlings or plants as they exist naturally because the claims do not particularly point out any non-naturally occurring products. While the claims recite that the seeds, seedlings or plants comprise "a polynucleotide which comprises a promoter operatively linked to a nucleic acid sequence encoding abscisic acid insensitive 5 (ABI5)", this limitation does not distinguish the claimed products from naturally occurring products, because naturally occurring *Arabidopsis* plants

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comprise a native polynucleotide which comprises a native promoter that is operatively linked to a native nucleic acid sequence encoding ABI5. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by amending the claims to indicated that the claimed products are transformed with an isolated or purified polynucleotide. See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 25, 27-29, 38 and 41-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Finkelstein et al. (The Plant Cell, April 2000, Vol. 12, pages 599-609, Applicant's IDS).

The claims are drawn to a seed, seedling or plant comprising a polynucleotide which comprises an inducible or derepressible promoter operatively linked to a nucleic acid sequence encoding abscisic acid insensitive 5 (ABI5), including a seed, seedling or plant that overproduces ABI5 in comparison to an untransformed plant, and a seed, seedling or plant that is hypersensitive to abscisic acid in comparison to an untransformed plant.

Finkelstein et al. teach transgenic *Arabidopsis* plants comprising a polynucleotide which comprises a native promoter operatively linked to a nucleic acid sequence encoding the protein encoded by the abscisic acid insensitive 5 locus of *Arabidopsis* (page 600 column 2 second full

paragraph; page 601 Table 1). The polynucleotide taught by Finkelstein et al. comprises a promoter which is both inducible and derepressible promoter because expression from the native promoter of the *Arabidopsis* ABI5 gene is developmentally regulated by native proteins that induce and derepress its transcriptional activity (page 604 Figure 5). The transgenic plants taught by Finkelstein et al. also overproduce ABI5 relative to the nontransformed *abi5* mutant plants, as mutant complementation was observed (page 605 Table 1). The transgenic plants taught by Finkelstein et al. are additionally hypersensitive to abscisic acid relative to the nontransformed *abi5* mutant plants (page 605 Table 1).

Claims 25, 27-29, 38 and 41-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Lopez-Molina et al. (Plant Cell Physiol. May 2000, Vol. 41, No. 5, pages 541-547, Applicant's IDS).

The claims are drawn to a seed, seedling or plant comprising a polynucleotide which comprises an inducible or derepressible promoter operatively linked to a nucleic acid sequence encoding abscisic acid insensitive 5 (ABI5), including a seed, seedling or plant that overproduces ABI5 in comparison to an untransformed plant, and a seed, seedling or plant that is hypersensitive to abscisic acid in comparison to an untransformed plant.

Lopez-Molina et al. teach transgenic *Arabidopsis* plants comprising a polynucleotide which comprises a native promoter operatively linked to a nucleic acid sequence encoding the protein encoded by the abscisic acid insensitive 5 locus of *Arabidopsis* (page 543 Table 1; page 545 column 1 first full paragraph). The polynucleotide taught by Lopez-Molina et al. comprises a promoter which is both inducible and derepressible promoter because expression from the native

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promoter of the *Arabidopsis* ABI5 gene is developmentally regulated by native proteins that induce and derepress its transcriptional activity (page 545 Figure 3). The transgenic plants taught by Lopez-Molina et al. also overproduce ABI5 relative to the nontransformed *abi5* mutant plants, as mutant complementation was observed (page 543 Table 1). The transgenic plants taught by Lopez-Molina et al. are additionally hypersensitive to abscisic acid relative to the nontransformed *abi5* mutant plants (page 543 Table 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Finkelstein et al. or Lopez-Molina et al. (Plant Cell Physiol. May 2000, Vol. 41, No. 5, pages 541-547, Applicant's IDS) in view of Kay et al. (Science, 5 June 1987, Vol. 236, No. 4806, pages 1299-1302).

The claims are drawn to a seed, seedling or plant comprising a polynucleotide which comprises a constitutive promoter operatively linked to a nucleic acid sequence encoding abscisic acid insensitive 5 (ABI5), including a seed, seedling or plant that overproduces ABI5 in comparison to an untransformed plant, and a seed, seedling or plant that is hypersensitive to abscisic acid in comparison to an untransformed plant.

The teachings of Finkelstein et al. (The Plant Cell, April 2000, Vol. 12, pages 599-609, Applicant's IDS) and Lopez-Molina et al. are set forth above.

Finkelstein et al. and Lopez-Molina et al. do not teach the use of a constitutive promoter.

Kay et al. teach a cauliflower mosaic virus 35S promoter that is constitutively active in several plant species and that consequently has been used to express a number of foreign genes in plants (page 1299 column 1 first paragraph). Kay et al. also teach a variant of the cauliflower mosaic virus 35S promoter with approximately ten-fold higher transcriptional activity than the native promoter useful for obtaining high levels of expression of operatively linked genes in transgenic plants (abstract; page 236 Figure 2).

It would have been obvious to one skilled in the art at the time the invention was made to make transgenic plants comprising a polynucleotide which comprises a constitutive promoter, such as the cauliflower mosaic virus 35S promoter taught by Kay et al., operatively linked to a nucleic acid sequence encoding ABI5, as taught by Finkelstein et al. and Lopez-Molina et al. One skilled in the art would have been motivated to express a nucleic acid sequence encoding ABI5 from a constitutive promoter in order to produce recombinant ABI5 protein in a quantity sufficient to characterize the protein, and to determine the biological role of the ABI5 protein in planta. Given the success of Finkelstein et al. and Lopez-Molina et al. in making transgenic *Arabidopsis* plants that comprise and express a nucleic acid sequence encoding ABI5, and given the success of Kay et al. in using the constitutive cauliflower mosaic virus 35S promoter to obtaining high levels of expression of operatively linked genes in transgenic plants, one skilled in the art would have been motivated to generate the claimed invention with a reasonable

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expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

Cynthia Collins 6/22/04